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| EXAMINER | |
|---|---|
| MCKENZIE, THOMAS C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1624 | |

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/898,809 | RAJAGOPALAN ET AL. | |
| | Examiner | Art Unit | |
| | Thomas McKenzie, Ph.D. | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *12-14 and 23-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 23-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



S.r.o-d

## DETAILED ACTION

1. This action is in response to a declaration and arguments filed on 5/9/05. Applicant has not amended any claims. There are no new claims. Claims 12-14 and 23-33 were previously rejected. This is the eighth action on the merits. The application concerns some uses of cyanine dye compositions.

### *Response to Amendment*

2. The declaration under 37 CFR 1.132 filed 5/9/05 by Professor Erlanger is insufficient to overcome the rejection of claim 12-14, 23-31, and 33 based upon indefiniteness, lack of enablement, and lack of written description as set forth in points #5, #6, #7, #8, and #9 the last Office action. Professor Erlanger's points will be considered in order beginning with his first substantive point, which is #7.

Before beginning the analysis of the declaration, Prof. Erlanger's impressive teaching and research experience are in the field of biochemistry and macromolecules. Two of his widely cited exemplary papers deal with substrates of the enzyme trypsin and antibodies that bind to DNA for example. Although Prof. Erlanger has an undergraduate and a master's degree in chemistry, he would appear to have no special expertise in medicinal chemistry, small molecule ligands, or in organic chemistry generally. The essence of all the rejections under discussion is whether the functional terms Applicants use to describe important parts of their

small molecules are well enough known to "permit one skilled in the art to immediately envisage the product claimed" as required by MPEP §2161 I. A.

In point #7 an opinion, based solely on the formula under dispute, is offered that Applicants had written description of their invention. According to the MPEP §716.0(c) III, "*In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of 35 U.S.C. 112 is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with 35 U.S.C. 112 are entitled to some weight)".

Point #8 of the declaration nicely restates, in compact form the issues under dispute. Point #9 offers the assertion that Applicants are enabled for making the functionally described molecules. The evidence for this assertion is unclear. In any case, assertions of enablement are not probative, *In re Knowlton* 183 USPQ 33 at 37, *In re BRANDSTADTER, KIENZLE, AND SYKES*, 179 USPQ 286 at 294.

In point #10, Prof. Erlanger suggests a perfectly reasonable method of finding the structures of many common steroids. Unfortunately, the issue is not the structure of steroids but of the structure of all "steroid receptor binding molecules". Most "steroid receptor binding molecules" are not steroids, not all steroids bind to any steroid receptor, and no steroid binds to every steroid receptor. For example there is a cottage industry set up to find the thousands and thousands of synthetic

and natural ligands of the estrogen steroid receptor. The compound diethylstilbesterol (DES) is not a steroid but strongly binds to the estrogen receptor. A book listing steroid structures would not disclose DES. The biological parent of the physiologically active steroids, cholesterol, does not bind to steroid receptors. The male steroid testosterone does not bind to the estrogen receptor. Neither testosterone nor esterone bind to the corticosteroid receptors and the corticosteroids, cortisone and aldosterone, do not bind to the sex hormone receptors. Thus, knowing the structures of all steroids does little to clarify which steroids bind to which steroid receptors and are embraced by Applicants' claim language.

In point #11, a method of attaching these steroids identified in the book "Fundamentals of Clinical Chemistry, 3rd Ed." through linker L to the DYE is presented. This is not on point because the enablement issue concerning making the compounds is not how to link them, once the E fragment has been identified. Rather it is the impossibility of making compounds where the structure of E is unknown and unknowable. In points #12 and #13 a method of attaching the steroid estradiol to DYE is presented. This is hardly commensurate in scope to the limitations, "somatostatin receptor binding molecule", "heat sensitive bacterioendotoxin receptor binding molecules", "neurotensin receptor binding

molecules", "bombesin receptor binding molecules", "cholecystekinin receptor binding molecules", "steroid receptor binding molecules", and "carbohydrate receptor binding molecule" which embraces thousands if not millions of compounds.

Point #14 offers the peptide octreotide as an example of a "somatostatin receptor binding molecule". Octreotide is not mentioned in the specification and frankly the Examiner has no idea how many other compounds bind to this receptor. The Examiner does not know where such binding data may be found and nothing in the specification or this declaration point to any source of such data. Point #15 offers the opinion, based on the single example of octreotide that the phrase "somatostatin receptor binding molecule" is definite and enabled for making compounds bearing such ligands. If the somatostatin receptor is like the steroid receptors, presumably thousands of such compounds exist. Again this single example is not commensurate in scope with the claims.

Point #16 corrects an error on the part of the Examiner concerning the meaning of "epitope". It is not the portion of a macromolecular chain that initiates antibody formation but has the broader meaning of that portion of a macromolecular chain that reacts to the antibody. The Examiner failed to take Prof. Erlanger's class while attending Columbia or any biochemistry class for that

matter and is grateful for the correction. The rejections have been modified to incorporate the correct meaning of "epitope".

In point #17 the fact that steroids, when attached to a macromolecular protein can form antibodies and can be epitopes is provided. Presumably steroids not attached covalently to proteins cannot form antibodies and by themselves are not epitopes. Do the "steroid receptor binding molecules" not include steroids themselves but only steroids covalently linked to a protein and able to act as an epitope? There is no limitation in the claims that radical E must be an epitope. The specification in lines 17-18, page 12 contains a statement that E must be an "epitope", which caused the confusion on the Examiner's part when he was attempting to learn the structure of E.

Point #18 asserts that correlation exists between the structure of the claimed E radicals and their functions. This is based on the ability of the sulfenate group, the –O-S-Ar group, to produce free radicals when the molecule containing the sulfenate group is irradiated with light. Since the structure and function of the sulfenate group is not at issue, this is not on point. Point #19 offers the legal conclusion that Applicants are not required to disclose the structures of the claimed E radicals. A steroid is offered as a choice for the "steroid receptor binding molecules", octreotide as a choice for the "somatostatin receptor binding

molecules", and bombesin as a choice for the "bombesin receptor binding molecules". Are Applicants limiting their choices for E to radicals derived from these three molecules? Or are any other molecules that happen to bind to these three receptors to be included? The issue is not the structure of a single compound fitting the claim limitations but rather the structures of all of them. In any case no weight is given to an opinion on the ultimate legal conclusions at issue, *In re Lindall* 155 USPQ 521, *In re Chilowsky* 134 USPQ 515.

Points #20 and #21 assert the conclusion that no particular binding affinity is required for a molecule to meet Applicants' claim limitation "steroid receptor binding molecules", *etc.* This is contrary to the requirements in MPEP §2173.05(b) concerning relative terminology, "[w]hen a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably appraised of the scope of the invention. Even if the specification uses the same term of degree as in the claim, a rejection may be proper if the scope of the term is not understood when read in light of the specification. While, as a general proposition, broadening modifiers are standard tools in claim drafting in order to avoid reliance on the

doctrine of equivalents in infringement actions, when the scope of the claim is unclear a rejection under 35 U.S.C. 112, second paragraph, is proper. See *In re Wiggins*, 488 F. 2d 538, 541, 179 USPQ 421". The word "binding" is a term of degree.

Point #22 asserts that Applicants do provide a method of assaying the binding of small molecules to the various receptors under discussion. Yet Prof. Erlanger does not point to a page and line in the specification where that assay may be found but rather cites one of his own papers. This paper is not cited in the specification and is not found on any IDS. Frankly, Prof. Erlanger must be agreeing with the Examiner that no such assay is taught within the four corners of the Application. The application must provide both written description and enablement when filed. These assays are critical to finding these elusive molecules that bind to the various receptors, yet no such procedure is taught within the specification. Applicants are reminded of the requirement in *Ex parte LANHAM* 135 USPQ 106, "[i]t is our opinion that the statutory requirement of a disclosure of utility must be found in the specification as originally filed and cannot be supplied by way of argument or affidavit. If appellant, in fact, knew of this particular utility for the product of his process, it should have been disclosed in the specification."

Point #23 asserts that Prof. Erlanger can immediately envision which molecules will bind to these various receptors and offers the opinion that a binding affinity of 1 μm would be sufficient affinity. The binding of different steroids to the various steroid receptors, of octreotide to the "somatostatin receptor binding molecules", and bombesin to the "bombesin receptor binding molecules" was discussed above. Other than these three, there is no explanation of how the binding of diethylstilbesterol (DES), for example, or the lack of binding of stilbesterol to the estrogen steroid receptor can be determined immediately without experimental work. The suggestion of 1 μm affinity is not found anywhere in the specification and is at odds with the statement of point #20 that "the inventors are not claiming any particular binding property".

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14, 23-31, and 33 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "somatostatin receptor binding molecule", "heat sensitive bacterioendotoxin receptor binding molecules", "neurotensin receptor binding molecules", "bombesin

receptor binding molecules", "cholecystekinin receptor binding molecules", "steroid receptor binding molecules", and "carbohydrate receptor binding molecule" are all indefinite. What are the chemical structures of these fragments that define radical "E"? These are not art-recognized structural terms. The passage spanning line 17, page 12 to line 12, page 13 lists the function that these radicals are to perform, but does not clarify the molecular structures intended. Applicants' statement that "E" is an epitope only further clouds the issue. The Examiner understands that an epitope is a portion of a macromolecule chain capable of reacting with an antibody. If only macromolecules can be epitopes, then how can steroid hormones and amino acids alone be epitopes? Are the synthetic biomolecules listed in lines 11-13, page 13 the only epitopes "E" or are there others?

Nowhere do Applicants provide any assays that could be used to determine such binding. Nowhere do Applicants state how strong the affinity of a molecule for each of these receptors must be for the molecule to fall within the claim limitations. Since the binding affinities of molecules for receptors are dependent upon the conditions of the assay such information is crucial for determining which molecules are embraced by Applicants' claims.

There is no evidence that "somatostatin receptor binding molecule" ... "carbohydrate receptor binding molecule" *etc.* had well-defined meaning to one of ordinary skill in the art of medicinal chemistry. When disputed terms have "no previous meaning to those of ordinary skill in the prior art[,] its meaning, then, must be found [elsewhere] in the patent". *J.T. Eaton &Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1570, 41 USPQ2d 1641.

Thus, the terms "somatostatin receptor binding molecule" ... "carbohydrate receptor binding molecule" *etc.* do not bring to mind a particular chemical structure. What is important is whether the term is one that is understood to describe structure, as opposed to a term that is simply a nonce phrase or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term "means for". In *Mas-Hamilton Group v. LaGard*, Inc., 48 USPQ2d 1010, the U.S. Court of Appeals Federal Circuit held that the terms "lever moving element" and "movable link member" recited in a patent to a high security combination lock were in means-plus-function form. "Although the term "element" may be recognized as structural in some fields of art, the Mas-Hamilton court noted that the patentee had not directed the court "to any evidence demonstrating that the district court erred in determining that the term 'lever moving element' lacks a reasonably well understood meaning" in the relevant art.

Id. at 1214. The court in Mas-Hamilton also upheld the district court's ruling that there was no evidence that the term "movable link member" had a well-understood meaning in the art. Accordingly, the court held that the limitation reciting a "movable link member for holding the lever out of engagement with the cam surface before entry of a combination and for releasing the lever after entry of the combination" was in means-plus-function format," *Lighting World Inc. v. Birchwood Lighting Inc.*, 72 USPQ2d 1344 at 1351. Are Applicants invoking the sixth paragraph of 35 U.S.C. 112 in their use of these functional terms?

4. Claims 12-14, 23-31, and 33 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specific phrase "carbohydrate receptor-binding molecule" is indefinite. There is an entire class of such carbohydrate receptors, quite possibly thousands, and generally poorly understood and characterized. How would one know if any molecule E bound to such a receptor without checking all such receptors?

5. Claim 32 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase, "E is a univalent radical that

is recognized by and binds to a target site on the tissue" is indefinite. What is the structure of this radical? What targets and which tissues are intended?

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 and 23-33 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing compounds with radical "E" being dihydroxyindolecarboxylic acid or the peptide Cytate, does not reasonably provide enablement for preparing all the other functionally described E binding molecules. The specification does not enable any person skilled in the art of organic synthesis to make the invention commensurate in scope with these claims.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims." *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*,

230 USPQ 546. The issue is synthesizing compounds whose structures are not known.

a) If E is an epitope from an antibody, raising all possible antibodies to the somatostatin receptor and locating all the possible epitope sites on these antibodies is an impossible task. Alternatively, screening all "hormones, amino acids, peptides, ... and aptamers" to determine if they bind to the receptors listed in claim 1 is an open-ended and potentially inconclusive research project. Locating the epitope on any particular antibody to a somatostatin receptor say, would a moderate degree of experimentation. However, all possible antibodies would have to be made because the individual epitope sites would differ. After this is done, each individual radical would have to be synthesized in a form that would allow attachment to the rest of the pictured molecule. Thus, the quantity of experimentation required is huge. b) The direction concerning the compounds claimed is found in Figure 2. In that figure, the radical "E" is described as "Biomolecule". Thus, Figure 2 does not appear to be a working example. There is neither direction given concerning the synthesis of "biomolecule" nor its attachment to the rest of the claimed formula. c) There are no working examples of a compound of formula given in claim 1. There is no procedure given to determine the affinity of any substance to the receptors listed in claim 1. d) The

nature of the invention is chemical synthesis, which involves chemical reactions. e) The state of the art for tumor binding agents is given in the references spanning line 22, page 13 to line 5, page 14. The state of the art is that even complete directions to a team of pharmacologist, enzymologists, and immunologists to search for radical "E", hardy constitute direct to the chemist of how to make these substances. f) The artisan using Applicants invention to prepare the compounds whose use is claimed would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. h) The breadth of the claims includes all the presently unknown list of functionally described radicals E embraced by claim 1. Reference AR teaches the use of an octapeptide which binds to the somatostatin receptor. A radical which derived from this peptide would fit the definition of "E" but is unclear if there additional such peptides or how the peptide Cytate was identified. The scope of the claimed subjected matter, as far as the "E" radical, is enormous.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue

experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

7. Claims 12-14 and 23-33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way to convey reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The issues concerning the meaning of phrases "somatostatin receptor binding molecule" ... "carbohydrate receptor binding molecule" and "E is a target binding unit that is recognized by and binds to a target site on the tissue" are discussed above. Claims 12 and 32 do not contain a complete generic formula.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of

ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406." Applicants have disclosed no species and have made no assertion that there is any correlation between the biological function of radical "E" and its structure.

As discussed above the phrase ""somatostatin receptor binding molecule" ... "carbohydrate receptor binding molecule" and "E is a target binding unit that is recognized by and binds to a target site on the tissue" are not art recognized in medicinal chemistry. According to the MPEP §2163.02 Standard for Determining Compliance With the Written Description Requirement,

> "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir.

> 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In *re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

Thus, the chemist of ordinary skill in the art, who would make Applicants' compounds, would not know what "somatostatin receptor binding molecule" ... "carbohydrate receptor binding molecule" and "E is a target binding unit that is recognized by and binds to a target site on the tissue" were. That chemist would not have understood the inventor to be in possession of the claimed compounds at the time of filing.

This case was filed before Applicants had a clear idea of the structures of their desired compounds, how to make their compounds, and use them. The specification provides broad areas of future research and speculation, inviting undue experimentation in learning how to use Applicants' invention. Applicants may well now be developing practical applications of their photosensitizers, but the question here is what application they possessed at the time of filing. Anything is possible but as the U.S. Patent and Trademark Office, Board of Patent Appeals

and Interferences wrote in *Bindra v. Kelly*, 206 USPQ 570 "*Probable* utility does not establish practical utility. Practical utility can, in our view, be established only by actual testing therefore, or by establishing such facts as would be convincing that such utility could be "foretold with certainty." *Blicke v. Treves*, supra, 112 USPQ at 475."

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). "It is only a definition of a useful result rather than a definition of what achieves that result." "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the

specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")".

Also found in MPEP §2161 II A 2 (a) is the requirement that "[a]n adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., U*niv. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

Applicants rely upon the declaration by Prof. Erlanger under 37 CFR 1.132 filed 5/9/05 to overcome these rejections. That declaration is discussed above.

***Conclusion***

8. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

9. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas McKenzie, Ph.D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.

**Thomas C. McKenzie, Ph.D.**
**Primary Examiner**
**Art Unit 1624**

TCMcK/me